

## NicOx, Bausch + Lomb Glaucoma Candidate BOL-303259-X Meets Primary Endpoint in Phase 2b Study

### Bausch + Lomb to Pursue Global Phase 3 Development Program

13 March 2012 - Sophia Antipolis, France and Madison, NJ, USA.

**Bausch + Lomb**, the global eye health company, and **NicOx S.A.** (NYSE Euronext Paris: COX) today announced positive top-line results from the phase 2b study conducted with BOL-303259-X, a novel nitric oxide-donating prostaglandin F2-alpha analog, in patients with open-angle glaucoma or ocular hypertension. BOL-303259-X (previously NCX 116) was licensed by NicOx to Bausch + Lomb in March 2010 (see NicOx and Bausch + Lomb press release dated March 3, 2010). Bausch + Lomb will pay a \$10 million milestone payment to NicOx and will initiate a global phase 3 development program for BOL-303259-X.

The phase 2b study met its primary efficacy endpoint and showed positive results on a number of secondary endpoints. The primary efficacy endpoint was the reduction in mean diurnal intraocular pressure (IOP) on day 28. BOL-303259-X consistently lowered IOP in a dose-dependent manner. Two of the four doses tested showed greater IOP reduction compared with Xalatan® 0.005%, with the differences reaching more than 1mmHg (statistical significance:  $p < 0.01$ ).

*"We know from several studies that every mmHg of IOP reduction is important, as it reduces the risk of developing glaucoma and progression of glaucoma,"* said **Robert N. Weinreb, M.D., Distinguished Professor and Chairman of Ophthalmology, University of California San Diego**. *"A safe and well-tolerated therapy that can better lower IOP compared to current prostaglandin therapies would be welcomed by both clinicians and patients."*

The most efficacious dose of BOL-303259-X also showed positive results on a number of secondary endpoints, including consistently better control of IOP over 24 hours on day 28 as well as a statistically significant greater percentage of responders vs. Xalatan® 0.005%, defined as patients achieving an IOP of 18mmHg or less. The responder rate was 68.7% for the most efficacious dose of BOL-303259-X, compared to 47.5% for Xalatan® 0.005% ( $p = 0.006$ ).

The safety of BOL-303259-X was comparable to Xalatan®. The most common adverse event was ocular hyperemia (red eye), which occurred at a similar rate across all treatment groups.

Bausch + Lomb initiated the randomized, investigator-masked phase 2b study in November 2010 to identify the most efficacious and safe dose of BOL-303259-X for the reduction of IOP. The study enrolled 413 patients across 23 sites in the United States and Europe. Patients were randomized to receive either BOL-303259-X (various concentrations) or Xalatan® 0.005% (latanoprost) once a day in the evening for 28 days.

*"Bausch + Lomb is committed to funding and developing innovative new medicines to benefit physicians and the patients they serve,"* said **Dan Wechsler, Executive Vice President and President, Global Pharmaceuticals, Bausch + Lomb**. *"BOL-303259-X adds to our growing portfolio of potential new products in eye health. We are encouraged by the positive results of our phase 2b study and hope that through further research and development, BOL-303259-X will provide a promising new treatment option for the millions of people around the world suffering from elevated IOP due to glaucoma or ocular hypertension."*

**Michele Garufi, Chairman and CEO of NicOx**, said, *"These positive results support the strong potential of our nitric oxide-donating platform in the ophthalmology field and we look forward to continuing to collaborate with the Bausch + Lomb team on the phase 3 development program."*

### NicOx and Bausch + Lomb Worldwide Licensing Agreement

In March 2010, NicOx and Bausch + Lomb signed a worldwide licensing agreement for BOL-303259-X for the potential treatment of glaucoma and ocular hypertension. Under the terms of the agreement, Bausch + Lomb made

an initial license payment to NicOx of \$10 million. In light of these positive results, Bausch + Lomb will pay an additional \$10 million milestone payment to NicOx and will initiate a global phase 3 development program for BOL-303259-X. NicOx stands to receive potential regulatory, commercialization and sales success-based milestones, which could total an additional \$162.5 million. NicOx will also receive tiered double-digit royalties on the sales of BOL-303259-X. NicOx has the option to co-promote BOL-303259-X products in the United States.

### **About Glaucoma**

Glaucoma is a group of eye diseases which can lead to the loss of peripheral vision and eventually total blindness. Glaucoma is frequently linked to abnormally high pressure in the eye (intraocular pressure, IOP), due to blockage or malfunction of the eye's drainage system. Abnormally high IOP does not cause any symptoms itself, however it can lead to optic nerve damage and vision loss if left untreated. Drug therapy is used to reduce IOP and therefore prevent further vision loss, typically through increasing the drainage of intraocular fluid by relaxing certain muscles in the eye. Several large trials have demonstrated that reducing IOP can prevent the progression of glaucoma in both early and late stages of the disease. A significant proportion of patients with elevated IOP require more than one medication to maintain their IOP within target levels, highlighting the need for more effective treatments.

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### **About NicOx**

NicOx (Bloomberg: COX:FP, Reuters: NCOX.PA) is a pharmaceutical company focused on the research, development and future commercialization of drug candidates. NicOx is applying its proprietary nitric oxide-donating R&D platform to develop an internal portfolio of New Molecular Entities (NMEs) for the potential treatment of inflammatory, cardio-metabolic and ophthalmological diseases.

The Company's pipeline includes several nitric oxide-donating NMEs, which are in development internally and with partners, who include Merck (known as MSD outside the United States and Canada), Bausch + Lomb and Ferrer.

NicOx S.A. is headquartered in France and is listed on Euronext Paris (Compartment C: Small Caps).



### **About Bausch + Lomb**

Bausch + Lomb is one of the best-known and most respected healthcare companies in the world. Its core businesses include contact lenses and lens care products, ophthalmic surgical devices and instruments, and ophthalmic pharmaceuticals. Founded in 1853, the company is headquartered in Rochester, N.Y., and employs more than 10,000 people worldwide. Its products are available in more than 100 countries. More information is available at [www.bausch.com](http://www.bausch.com).

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**This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated in the forward-looking statements.**

Risks factors which are likely to have a material effect on NicOx's business are presented in the 4<sup>th</sup> chapter of the « *Document de référence, rapport financier annuel et rapport de gestion 2011* » filed with the French Autorité des Marchés Financiers (AMF) on February 29, 2012 and available on NicOx's website ([www.nicox.com](http://www.nicox.com)) and on the AMF's website ([www.amf-france.org](http://www.amf-france.org)).

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